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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,978	06/15/2006	Morten Bryhn		8212

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EXAMINER	
BETTON, TIMOTHY E	
ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/582,978	BRYHN ET AL.	
	Examiner	Art Unit	
	TIMOTHY E. BETTON	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-22,37-46 and 49-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-22,37-46 and 49-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9 June 2009 has been entered.

Claims at Issue

Claims 13-22, 37-46, and 49-52 are pending in this application.

Response to Arguments

Applicants' arguments filed on 9 June 2009 have been acknowledged and duly made of record.

Principally, applicants' aver the inherency of Brevik et al. employed in the rejection under U.S.C. 35 § 102 (b).

Specifically, applicants' allege that Breivik et al. has not clearly delineated the relationship between obesity and hypertriglyceridemia.

Upon further reconsideration, the same rejection is hereby withdrawn.

Applicants' aver the obviousness of Brevik et al. and Corkey et al. over the instant invention as employed in the current rejection under U.S.C. 35 § 102 (b). In view applicants' discussion of the Corkey et al., the Examiner considers applicants' reasonable confusion with regard to the Examiner's inadvertent misprint. Upon further consideration of the scope and content of Corkey et al., the said reference is maintained because it is sufficient for what it shows. The obvious intent in Corkey et al. is for an expectation of success with the required

standard amount of EPA and DHA in consideration of the target population being treated, i.e., infant and child principally (emphasis added) and adults. It is art-known, in hospital settings that pediatric dosing has to be calibrated seamlessly with essentially no margin of error, negligible or otherwise to the decimal. Corkey et al. further supports and suggests that an individual administered these specific components in preferred and/or standard formulations would reasonably achieve the same claimed results of applicants' invention.

Breivik et al. is averred by applicants in this instance for allegedly failing to teach or even suggest a treatment for obesity. Applicants' argument is considered but is not found persuasive because though Breivik et al. does not go into specific detail as to risks of cardiovascular disease, Corkey et al. does, however, address a clear linking of the two disorders.

Applicants' further assert that Breivik et al. does not support or suggest the disclosed ratios according the instant invention. However, the Examiner wishes to direct applicants' attention specifically to claims 14, 15, 38, 41, and 50 which discloses the limitation of [wherein] *a fatty acid composition is 1:X, where X is equal or larger than 1.* There is no suggestion in the current claim set that '*DHA rich'* would not reasonably extend to a ratio as disclosed of 1:1 as supported by Breivik et al. The alleged silence in Corkey et al. to teach EPA: DHA ratios is resolved by the primary teachings of Breivik et al. which not only teach embodiments drawn to EPA and DHA in obviousness over claimed invention but also clearly teach a use which reasonably intends toward an expectation of success via the subject matter drawn to the reduction of cardiovascular risks.

Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13-22, 37-46, and 49-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breivik et al. (USPN 5,502,077) in view of Corkey et al.

Breivik et al. teach a fatty acid composition comprising at least 80% by weight of omega-3-fatty acids, salts or derivatives thereof, wherein (all-Z)-5,8,11,14,17-eicosapentaenoic acid (EPA) and (all-Z)-4,7,10,13,16,19-docosahexaenoic acid comprises at least 75% by weight of the total fatty acids. The compositions can be used for the ***treatment*** [...] of multiple risk factors for cardiovascular diseases (abstract only).

Breivik et al. teach that present invention relates to a fatty acid composition comprising at least 80% by weight of omega-3 polyunsaturated fatty acids, wherein at least 75% by weight of the total fatty acids comprise omega-3 (all-Z)-5,8,11,14,17-eicosapentaenoic acid (EPA)C 20:5 and (all-Z)-4,7,10,13,16,19-docosahexaenoic acid (DHA) C 22:6 9column 1, lines 5-10).

Breivik et al. teach the same and exact preferred ratio limitation in the instant claims. The upgrading of the EPA fraction to obtain a weight ratio of EPA: DHA of from 1:1 to 2:1, especially 3:2 or the upgrading of the DHA fraction to obtain an EPA: DHA weight ratio of from 1:1 to 1:2 may be achieved in the molecular distillation stage. The method also provides the possibility of using supercritical fluid extraction and/or chromatography in the second stage with CO.sub.2 eventually containing a more polar modifier, such as ethanol, in order to concentrate the EPA and/or DHA fraction (column 3, lines 61-67; column 4, lines 1 and 2).

Breivik et al. teach fish oil which is of animal origin (column 1, line 38). This limitation of oil also anticipates the limitation in the claims drawn to a liquid form (claim 51).

Breivik further anticipates the claimed invention by teaching that this preferred ratio of EPA: DHA has an advantageous effect on risk factors for cardiovascular diseases (column 2, lines 50-67).

Breivik et al. teaches an esterified formulation comprising EPA: DHA (column 3, lines 2-39).

Breivik et al. does not go into specific detail as to risks of cardiovascular disease in view of the specific treatment thereof.

However, Corkey et al. essentially teach dietary products for infant child and adult nutrition which possess adequate levels and **ratios of medium chain fatty acids and .omega.-polyunsaturated fatty acids.** Consumption of these dietary products can contribute to the prevention of obesity in developing individuals and can contribute to a **reduction in body fat mass in individuals who are trying to loose weight or reduce body fat mass (e.g., obese individuals)**. A first preferred product is a dairy supplement or formulated dairy product for consumption by infants or children to prevent development of obesity. A second preferred product is a **dietary supplement** for persons combating unwanted weight gain or obesity. Also featured are methods of formulating these dietary products (abstract only).

Corkey et al. teach a combination of MCFA and DHA Reduces Lipogenesis, Lipid Storage, and Secretion from Liver Cells (Please see example 12, paragraphs 121 and 122).

Corkey et al. teach dietary supplements and products aimed at preventing obesity, reducing fat mass, and/or reducing serum TGs (in particular, serum TGs associated with traditional MCT diets) [0006].

Corkey et al. teach […].Because the .omega.-3 long chain fatty acids (EPA:DHA) have been shown to efficiently inhibit fatty acid synthesis, it is proposed that mixing MCFA with a small portion of EPA and DHA will synergize the positive effects of both types of fatty acids in reducing fat storage in adipose tissue and fat product [0121].

Corkey et al. teach a dietary regimen to be incorporated concomitantly with the said weight-reduction formulation. The present invention features dietary supplements and products aimed at preventing obesity, reducing fat mass, and/or reducing serum TGs (in particular, serum TGs associated with traditional MCT diets) [0006]; [0034].

Corkey et al. teach a triglyceride form of the formulation. A glyceride is an ester of glycerol (1, 2, 3-propanetriol) with acyl radicals of fatty acids and is also known as an acylglycerol. If only one position of the glycerol molecule is esterified with a fatty acid, a "monoglyceride" is produced; if two positions are esterified, a "diglyceride" is produced; and if all three positions of the glycerol are esterified with fatty acid a “triglyceride” or "triacylglycerol" is produced. A glyceride is called "simple" if all esterified positions contain the same fatty acid; or "mixed" if different fatty acids are involved. The carbons of the glycerol backbone are designated sn-1, sn-2 and sn-3, with sn-2 being in the middle and sn-1 and sn-3 being the ends of the glycerol [0033].

Thus, it would be *prima facie* obvious to one of ordinary skill in the art to at once recognize a reasonable expectation of success via the incorporating together the methods and teachings of Breivik et al and Corkey et al. Determining the scope and contents of the prior art in view of the immediate references *supra* has been reasonably assessed.

Consummately, the Breivik et al. reference teaches the current invention. The specificities drawn to a particular target population suffering from specific risks and disorders associated with cardiovascular diseases in need of such formulations are adequately supported and taught by Corkey et al.

Accordingly, the level of ordinary skill in the pertinent art suggests well-known and well-established protocols which are sufficiently described, defined, and explained in the references above. As a result, the inventive objective of current invention is made obvious. In consideration of the objective evidence present in the current application, it would have been *prima facie* obvious to combine the references together in obviousness over the claimed invention.

In view of the differences, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to employ the fatty acid composition for treating persons with obesity because it is well-established in the art that the administration of such supplements aid in the treatment of weight control. Based on the secondary reference, Corkey et al. teach ratios of medium chain fatty acids and .omega.-polyunsaturated fatty acids. Further, the said reference teaches consumption of these dietary products [which] can contribute to the prevention of obesity in developing individuals and can contribute to a reduction in body fat mass in individuals who are trying to loose weight or reduce body fat mass (e.g., obese individuals). Accordingly, the reference of Corkey et al. reads on dietary formulations of the said fatty acids.

Similarly, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make a dietary composition either in the form of a snack or

emulsion. Accordingly, the reference of Corkey et al. reads on dietary formulations of which the said fatty acids are comprised.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY E. BETTON whose telephone number is (571)272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TEB

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